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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,491	11/05/2003	Ali Amara	03495.0300	6283

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,491

Applicant(s)

AMARA ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 and 72-100 is/are pending in the application.
- 4a) Of the above claim(s) 31, 72-77, 86 and 90-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30, 32-34, 78-85, 87-89 and 96-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed April 28, 2005 is acknowledged and entered. Claims 23-34 and new claims 72-100 are pending. Claims 23-30, 32-34, 78-85, 87-89 and 96-100 are under examination. Claims 31, 86, 72-77 and 90-95 are withdrawn from consideration, being drawn to non-elected inventions. Applicant requests rejoinder of the non-elected inventions should the linking claims be found allowable. In response, rejoinder will be considered in due course.
2. The objection to claims 1 and 38 for failing to spell out the acronyms DC-SIGN and HIV is moot because the claims 1 and 38 have been cancelled. It is noted that amended claim 23, the first independent claim, spells out DC-SIGN.
3. The rejection of claims 38-41 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating human immunodeficiency virus type 1 (HIV-1) infection, does not reasonably provide enablement for preventing all types of HIV infections, is moot because these claims have been cancelled.
4. The rejection of claims 1, 2, 4-6, 9-20, 23-30 and 32-41 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is moot with regard to the cancelled claims, and withdrawn with regard to the pending claims that have been amended to delete the term, "substantially".
5. The following art rejections are withdrawn or moot in view of Applicant's cancellation of claims or amendment:

- The rejection of claims 1, 2, 4-6, 9-20, 38, 39 and 41 35 U.S.C. 102(a) as being anticipated by Littman *et al.* (US Patent 6,391, 567 B1)

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- The rejection of claims 1, 2, 4, 6, 9-17, 38, 39 and 41 under 35 U.S.C. 102(b) as being anticipated by Littman *et al.* (WO 01/64752 A2)
 - The rejection of claims 1, 2, 4, 5, 9-12, 15-18, 38, 39 and 41 under 35 U.S.C. 102(b) as being anticipated by Figdor *et al.* (EP 1046651 A1)
 - The rejection of claims 1, 2, 4, 6, 9-16, 19, 20, 23, 25-30, 32-33, 36 and 37 under 35 U.S.C. 102(b) as being anticipated by Brandriss *et al.* (*J. Gen. Virology*, 1986, 67:229-234).
 - The rejection of claims 24 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brandriss as applied to claims 1, 2, 4, 6, 9-16, 19, 20, 23, 25-30, 32-33, 36 and 37 above, and further in view of Hoogenboom *et al.* (US Patent 5,565,332).
6. The rejection of claims 1, 2, 9-14, 38, 39 and 41 as provisionally rejected under 35 U.S.C. 101 for claiming the same invention as that of claims 1, 2, 9-14, 39, 41 and 42 of copending Application No. 10/700,507, is withdrawn in view of Applicant's amendment limiting the scope of the claims to *Flaviviridae* virus infection and excluding HIV and SIV.

Claim Rejections - 35 USC § 112

7. Claims 23-30, 32-34, 78-85, 87-89 and 96-100 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a *Flaviviridae* virus infection, does not reasonably provide enablement for treatment wherein the inhibition of binding between the *Flaviviridae* virus and the effector molecule by greater than 80%. The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The breadth of the claims is unreasonable, encompassing the inhibition of binding between the *Flaviviridae* virus and the effector molecule by greater than 80%. The family of flaviviruses includes for example, Hepatitis C (HCV), Yellow fever, Dengue, Japanese encephalitis, tick-borne encephalitis, pestivirus, border disease and classical swine fever virus. The nature of the invention encompasses 80% binding inhibition of any of these viruses of the flavivirus family by blocking entry of these viruses into cells by preventing DC-SIGN from binding to the viruses. It is noted that the claims are now drawn to treatment, not prevention of *Flaviviridae* virus infection. However, it is useful to review the state of the art with regard to attempts to prevent and treat *Flaviviridae* virus infection. The state of the art shows that there are no vaccines for flaviviruses. For example, the Centers for Disease Control (CDC) reports that there is no vaccine for Dengue virus and that efficacy trials in humans have yet to be initiated as of the year 2003 (see website printout, page 4, "Future Outlook" section). Leyssen *et al.* (*Clin. Microbiol. Rev.* 2000, 13(1):67-82, herein, "Leyssen") confirms that there are no vaccines or treatments for Dengue virus (page 72, column 1, first full paragraph). Current treatment for HCV is ribavirin, but with limited results and no protection (Leyssen, page 72, top incomplete paragraph). Leyssen teaches that little is known about flavivirus entry and cell receptor (page 73, columns 1 and 2, bridging paragraph). Leyssen also discloses that because of "the genetic and serological heterogeneity of HCV, the development of effective vaccines will be difficult and is not expected to occur soon" (page 76, column 2, last paragraph). Regarding Dengue virus, Japanese encephalitis virus and tick-borne encephalitis virus, Leyssen discloses

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that there are no drugs yet available (page 76, column 2, last paragraph). Men *et al.* (*J. Virology*, 2004, 78(9):4665-4674) also confirms that there are no vaccines for Dengue virus (abstract).

Given the prior art's teachings regarding treatments or lack of treatments for *Flaviviridae* virus infection, the instant claims are likely to treat *Flaviviridae* virus infection at some level. *The Office takes the position that even though the "treatment" does not result in 80% binding inhibition, some binding will have been inhibited and thus the claims are enabled for this definition of "treatment" wherein some binding is inhibited.* The level of skill in the art is high. The level of predictability in the art is low, evidenced by the above discussion of the state of the art. The specification does not provide guidance or working examples of 80% binding inhibition of *Flaviviridae* virus in an acceptable animal model. It would require undue experimentation to use the claimed invention to treat *Flaviviridae* virus infections such that 80% of binding between the *Flaviviridae* virus and the effector molecule is inhibited. Therefore, the claims are not enabled for their full scope. It is suggested that claims limitations referring to percent inhibition be removed from the claims in order to overcome this rejection.

Conclusion

8. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen
July 20, 2005



JAMES HOUSEL 7/25/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600